

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

CAVALERI et al.

Serial No.: Not yet assigned

Filed: Submitted herewith

For: METHODS OF ADMINISTERING
DALBAVANCIN FOR TREATMENT
OF SKIN AND SOFT TISSUE
INFECTIONS

Group Art Unit: Not yet assigned

INFORMATION DISCLOSURE STATEMENT

MAIL STOP PATENT APPLICATION

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97–1.98, information relating to the above-identified application is hereby disclosed. The accompanying Form PTO–1449 provides a listing of documents that may be relevant to the subject application.

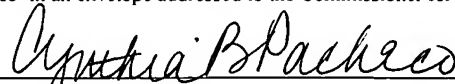
It is requested that the Examiner fully consider the art cited in the accompanying Form 1449, initial the left-most column of the form adjacent each cited reference, and return a copy for Applicants' records. It is further requested that the art be cited on the cover of any patent issuing from the subject application.

CERTIFICATE OF MAILING (37 C.F.R. §1.10)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as 'Express Mail Post Office To Addressee' in an envelope addressed to the Commissioner for Patents, PO Box 1450 Alexandria, VA 22313-1450.

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April 16, 2004
Date of Deposit


Cynthia B. Pacheco

In accordance with §1.97(b), this Information Disclosure Statement is being filed within three months of the filing date of the above-identified application, and therefore no fee is required.

In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the Patent and Trademark Office in one or more of the prior U.S. Application Serial No. 10/714,261, filed November 14, 2003, which claims the benefit of U.S. Provisional Patent Application Serial Nos. 60/427,654, filed November 18, 2002, 60/485,694, filed July 8, 2003, 60/495,048, filed August 13, 2003, and 60/496,483, filed August 19, 2003, by CAVALERI, et al. for which a claim for priority under 35 U.S.C. §120 has been made in the instant application. Accordingly, Applicants will provide duplicate copies in respect of the present case only if the Examiner so desires.

This statement should not be construed as a representation that more material information does not exist or that an exhaustive search of the relevant art has been made. Nor does this statement constitute an admission by Applicants or Applicants' agent that the information provided herein is necessarily prior art to Applicants' invention. Moreover, Applicants reserve the right to establish the patentability of the claimed invention over any of the listed documents should they be applied there-against as references. Please charge any deficiency or credit any overpayment to Deposit Account No. 50-2862.

Respectfully submitted,

O'MELVENY & MYERS LLP

Dated: April 16, 2004

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Form PTO-1449

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

(Use several sheets if necessary)

Docket No. 892,280-147

Application No.: Not Yet Assigned

Applicant: CAVALERI et al.

Filing Date: Submitted herewith

Group Art Unit: Not Yet Assigned

Mailing Date: April 16, 2004

U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	03/25/1980	4,195,079	Celmer et al.			
	2.	12/16/1980	4,239,751	Coronelli et al.			
	3.	09/17/1985	4,542,018	Borghi et al.			
	4.	04/28/1987	4,661,470	Malabarba et al.			
	5.	11/01/1988	4,782,042	Selva et al.			
	6.	09/19/1989	4,868,171	Selva et al.			
	7.	11/21/1989	4,882,313	Sitrin			
	8.	04/03/1990	4,914,187	Malabarba et al.			
	9.	06/19/1990	4,935,238	Selva et al.			
	10.	09/04/1990	4,954,483	Malabarba et al.			
	11.	07/09/1991	5,030,619	Hector			
	12.	11/12/1991	5,064,811	Borghi et al.			
	13.	02/25/1997	5,606,036	Hermann et al.			
	14.	05/12/1998	5,750,509	Malabarba et al.			
	15.	12/01/1998	5,843,679	Selva et al.			
	16.	03/16/1999	5,882,900	Rizzo et al.			
	17.	04/06/1999	5,891,869	Lociuro et al.			
	18.	07/20/1999	5,925,550	Lancini et al.			
	19.	08/10/1999	5,935,238	Talcott et al.			
	20.	12/28/1999	6,008,225	Lociuro et al.			
	21.	11/07/2000	6,143,739	Lociuro et al.			
	22.	04/17/2001	6,218,505	Panzone et al.			
	23.	05/07/2002	6,384,013	Burkhardt et al.			

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FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO	
	24.	02/16/1983	EP 0 071 970	Europe				
	25.	11/30/1983	EP 0 095 154	Europe				
	26.	04/16/1986	EP 0 177 882	Europe				
	27.	12/10/1986	EP 0 204 179	Europe				
	28.	07/08/1987	EP 0 228 015	Europe				
	29.	10/14/1987	EP 0 240 609	Europe				
	30.	03/16/1988	EP 0 259 781	Europe				
	31.	02/01/1989	EP 0 301 785	Europe				
	32.	05/24/1989	EP 0 316 712	Europe				
	33.	07/04/1990	EP 0 376 041	Europe				
	34.	02/03/1993	EP 0 525 499	Europe				
	35.	10/15/1997	EP 0 801 075	Europe				
	36.	07/28/1999	EP 0 931 834	Europe				
	37.	12/21/1983	GB 2 121 401	Great Britain				
	38.	02/15/1984	GB 2 142 234	Great Britain				
	39.	02/01/1989	JP 1050900	Japan			Abstract	
	40.	04/21/1988	WO 88/02755	WIPO				
	41.	10/04/1990	WO 90/11300	WIPO				

OTHER DOCUMENTS

(including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	Title
	42.	Abramson, M.A. and Sexton, D.J. (1999). "Nosocomial Methicillin-Resistant and Methicillin-Susceptible <i>Staphylococcus Aureus</i> Primary Bacteremia: At What Costs?" <i>Infect. Control Hosp. Epidemiol.</i> 20(6): 408-411.
	43.	Adamczyk, M. et al. (1999). "Investigations Into Self-Association of Vancomycin Covalent Dimers Using Surface Plasmon Resonance Technology," <i>Bioorganic & Medicinal Chemistry Letters</i> 9:2437-2440.

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44.	Ahrendt, K.A. et al. (2003). "Identification of Potent and Broad-Spectrum Antibiotics from SAR Studies of a Synthetic Vancomycin Analogue," <i>Bioorganic & Medicinal Chemistry Letters</i> 13:1683-1686.
45.	Allen, N.E. and Nicas, T.I. (2003). "Mechanism of Action of Oritavancin and Related Glycopeptide Antibiotics," <i>FEMS Microbiology Reviews</i> 26:511-532.
46.	Anderegg, T.R. et al. (2003). "Initial Quality Control Evaluations for Susceptibility Testing of Dalbavancin (BI397), an Investigational Glycopeptide with Potent Gram-Positive Activity," <i>J. Clin. Microbiol.</i> 41(6): 2795-2796.
47.	Anderegg, T.R. et al. (2003). "Multicenter Quality Control Evaluation Results for Dalbavancin (BI 397), An Investigational Glycopeptide with Potent Gram-Positive Activity," <i>ASM May 2003, Poster No. A-090</i> , one page.
48.	Arimoto, H. et al. (1999). "Multi-Valent Polymer of Vancomycin: Enhanced Antibacterial Activity Against VRE," <i>Chem. Commun.</i> 1999:1361-1362.
49.	Arimoto, H. et al. (2001). "Affinity of a Vancomycin Polymer with Bacterial Surface Models," <i>Tetrahedron Letters</i> 42:3347-3350.
50.	Arioli, V. et al. (1976). "Gardimycin, A New Antibiotic From <i>Actinoplanes</i> : III. Biological Properties," <i>Journal of Antibiotics</i> 29(5):511-515.
51.	Arthur, M. and Courvalin, P. (1993). "Genetics and Mechanisms of Glycopeptide Resistance in Enterococci," <i>Antimicrobial Agents and Chemotherapy</i> 37(8):1563-1571.
52.	Author unknown. (2001). "Dalbavancin tested for soft tissue infections," located at < http://www.qxhealth.com/news_archive/cfm/search_details.cfm?sum_ID=8777 > last visited on September 8, 2003, one page.
53.	Author unknown. (2000). "Molecule of the Month V-Glycopeptide," located at < http://www.prous.com/mom/nov_00/mom.html > last visited on August 27, 2002, two pages.
54.	Author unknown. (2002). "Dalbavancin: The Staph Drug," located at < http://www.versicor.com/products/dalbava.html > last visited on August 27, 2002, one page.
55.	Author unknown. (2002). "Treatment Hope for Bloodstream Infections Introduced in Five Percent of Intravenous Catheter Cases," <i>www.biosearch.it</i> , one page.
56.	Barna, J.C.J. and Williams, D.H. (1984). "The Structure and Mode of Action of Glycopeptide Antibiotics of the Vancomycin Group," <i>Ann. Rev. Microbiol.</i> 38:339-357.
57.	Biavasco, F. et al. (2000). "Glycopeptide Susceptibility Profiles of <i>Staphylococcus Haemolyticus</i> Bloodstream Isolates," <i>Antimicrobial Agents and Chemotherapy</i> 44(11): 3122-3126.
58.	Campbell, K.C.M. et al. (2003). "Audiologic Monitoring for Potential Ototoxicity in a Phase I Clinical Trial of a New Glycopeptide Antibiotic," <i>J. Amer. Acad. Audiology.</i> 14(3):157-168.
59.	Candiani, G. et al. (1999). "In-Vitro and In-Vivo Antibacterial Activity of BI 397, a New Semi-Synthetic Glycopeptide Antibiotic," <i>J. Antimicrob. Chemother.</i> 44:179-192.

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	60.	Cavaleri, M. et al. (2002). "Protein Binding of Dalbavancin Using Isothermal Titration Microcalorimetry," <i>42nd ICAAC Abstracts</i> , San Diego, CA, September 27-30, 2002. Abstract No. A-1385, pg. 18.	
	61.	Cavaleri, M. et al. (2002). "Protein Binding of Dalbavancin Using Isothermal Titration Microcalorimetry," <i>42nd ICAAC</i> , San Diego, CA, September 27-30, 2002. Poster No. A-1385 , one page.	
	62.	Chaix, C. et al. (1999). "Control of Endemic Methicillin-Resistant <i>Staphylococcus Aureus</i> ," <i>JAMA</i> 282(18):1745-1751.	
	63.	Crowe, M. et al. (1998). "Bacteraemia in the Adult Intensive Care Unit of a Teaching Hospital in Nottingham, UK, 1985-1996," <i>Eur. J. Microbiol. Infect. Dis.</i> 17: 377-384.	
	64.	Darouiche, R.O. and Mansouri, D.M. (Date Unknown). "Dalbavancin Versus Vancomycin for Prevention of <i>Staphylococcus aureus</i> Colonization of Devices in an Animal Model," Poster #174 , one page.	
	65.	Dorr, M.B. et al. (2002). "Rationale for Once Weekly Dosing of Dalbavancin, a New Semisynthetic Glycopeptide," <i>Abstracts of the IDSA 40th Annual Meeting</i> , October 24 - 27, 2002. Abstract No. 52, pg. 53.	
	66.	Dorr, M.B. et al. (2002). "Rationale for Once Weekly Dosing of Dalbavancin, a New Semisynthetic Glycopeptide," <i>Abstracts of the IDSA 40th Annual Meeting</i> , October 24 - 27, 2002. Poster No. 52 , one page.	
	67.	Dowell, J. et al. (2003). "Dalbavancin Dosage Adjustments Not Required for Patients with Mild Renal Impairment," <i>ECCMID: Clinical Microbiology and Infection</i> , Abstract No. P1224. Vol. 9(Supp. 1), p. 291.	
	68.	Dowell, J. et al. (2003). "Dalbavancin Dosage Adjustments Not Required for Patients with Mild Renal Impairment," <i>ECCMID: Clinical Microbiology and Infection</i> , Poster No. P1224 , one page.	
	69.	Dowell, J.A. et al. (2002). "The Pharmacokinetics and Renal Excretion of Dalbavancin in Healthy Subjects," <i>42 ICAAC Abstracts</i> , San Diego, CA, September 27-30, 2002. Abstract No. A-1386, pg. - 18.	
	70.	Dowell, J.A. et al. (2002). "The Pharmacokinetics and Renal Excretion of Dalbavancin in Healthy Subjects," <i>42 ICAAC</i> , San Diego, CA, September 27-30, 2002. Poster No. A-1386 , one page.	
	71.	Dowell, J.A. et al. (2003). "Dalbavancin (DAL) Pharmacokinetics (PK) in Subjects With Mild or Moderate Hepatic Impairment (HI)," <i>43rd. Annual ICAAC</i> , Chicago, IL, September 14-17, 2003. Poster #A-19 , one page.	
	72.	Ednie, L. et al. (2003). "Antistaphylococcal Activity of Dalbavancin Compared to Those of Six Other Agents," <i>43rd. Annual ICAAC</i> , Chicago, IL, September 14-17, 2003, Poster #C1-1631 , one page.	
	73.	Fieser, L.F. and Fieser, M. (1967). <i>Reagents for Organic Synthesis</i> John Wiley and Sons, Inc. pp. 128-130.	
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PTO/SB/ 08 (2-92)		Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE	

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74.	Fridkin, S.K. et al. (2003). "Epidemiological and Microbiological Characterization of Infections Caused by Staphylococcus Aureus with Reduced Susceptibility to Vancomycin, United States, 1997-2001," <i>Clinical Infectious Diseases</i> 36: 429-439.
75.	Ge, M. et al. (1999). "Vancomycin Derivatives That Inhibit Peptidoglycan Biosynthesis Without Binding D-Ala-D-Ala," <i>Science</i> 284:507-511.
76.	Goldstein, B.P. et al. (1994). "Comparative Antibacterial Activity of Semi-Synthetic Derivatives of the Glycopeptide Antibiotic A40926 (MDL 62,476)," <i>Abstracts of the 34th ICAAC</i> Orlando FL October 4-7, 1994 Abstract No. F142 pg. 225.
77.	Goldstein, D. (May 10, 2001). "Versicor, Inc. Will Host Conference Call to Discuss Advanced Clinical Development Programs For Lead Antifungal and Antibiotic Products." Press Release, two pages.
78.	Goldstein, D. and Halsey, K. (November 28, 2001). "Versicor Announces Plans to Develop Dalbavancin As The First Once-Weekly Injectable Antibiotic." Press Release, three pages.
79.	Goldstein, D. and Halsey, K. (December 17, 2001). "Versicor Announces Data Demonstrating Tolerability of Anidulafungin at Higher Doses." Press Release, three pages.
80.	Goldstein, D. and Halsey, K. (March 12, 2002). "Versicor Announces Start of Phase II Study of Once-Weekly Dalbavancin for Bloodstream Infections." Press Release, three pages.
81.	Goldstein, D. and Halsey, K. (May 21, 2002). "Versicor Announces Completion of Phase II Study of Once-Weekly Dalbavancin for Skin and Soft Tissue Infections." Press Release, three pages.
82.	Goldstein, D. et al. (May 22, 2001). "Versicor Begins Phase II Trial of Dalbavancin, Its Noval Glycopeptide Antibiotic." Press Release, three pages.
83.	Goldstein, D. et al. (December 17, 2001). "Versicor Announces Positive Phase I Data for Dalbavancin, Demonstrating Feasibility of Once-Weekly Dosing." Press Release, four pages.
84.	Goldstein, D. et al. (September 5, 2002). "Versicor Announces Positive Phase 2 Study Results With Dalbavancin For Skin and Soft Tissue Infections." Press Release, three pages.
85.	Goldstein, D. et al. (September 19, 2002). "Versicor Announces 24 Abstracts to be Presented at Annual ICAAC Meeting Next Week." Press Release, three pages.
86.	Goldstein, D. et al. (October 23, 2002). "Versicor Announces Data Presentations Highlighting Advanced Product Candidates at IDSA Annual Meeting." Press Release, three pages.
87.	Goldstein, D. et al. (December 17, 2002). "Versicor Begins Phase III Trials of Dalbavancin for Skin and Soft Tissue Infections." Press Release, three pages.
88.	Goldstein, E.J.C. and Citron, D.M. (2002). "In Vitro Activities of Dalbavancin and Nine Comparator Agents against Fastidious and Anaerobic Gram-Positive Species," <i>42nd ICAAC Abstracts</i> , San Diego, CA, September 27 - 30, 2002. Abstract No. E-1454, pg. 163.

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	89.	Goldstein, E.J.C. et al. (2003). "In Vitro Activities of Dalbavancin and Nine Comparator Agents against Anaerobic Gram-Positive Species and Corynebacteria," <i>Antimicrob. Agents and Chemother.</i> 47(6): 1968-1971.	
	90.	Greene, T. W. (1981). <u>Protective Groups in Organic Synthesis</u> John Wiley and Sons, Inc. pp. ix-x (Table of Contents Only.)	
	91.	Griffin, J.H. (2003). "Multivalent Drug Design, Synthesis and In Vitro Analysis of an Array of Vancomycin Dimers," <i>JACS</i> 125:6517-6531.	
	92.	Hackbarth, C.J. et al. (1999). "In Vitro Activity of the Glycopeptide BI 397 Against <i>Staphylococcus aureus</i> and <i>Staphylococcus epidermidis</i> ," <i>39th Annual ICAAC</i> , San Francisco, CA. September 1999. Abstract No. 1283, pg. 332.	
	93.	Hackbarth, C.J. et al. (1999). "In Vitro Activity of the Glycopeptide BI 397 Against <i>Staphylococcus aureus</i> and <i>Staphylococcus epidermidis</i> ," <i>39th Annual ICAAC</i> , San Francisco, CA. September 1999. Poster No. 1283 , one page.	
	94.	Hackbarth, C.J. et al. (2001). "Antibacterial Activity of V-Glycopeptide (VER001), A Semi-Synthetic Glycopeptide, Against <i>Staphylococcus aureus</i> ," <i>ASM</i> , May 2001. Abstract No. A-4.	
	95.	Hackbarth, C.J. et al. (2001). "Antibacterial Activity of Dalbavancin (VER-001), A Semi-Synthetic Glycopeptide, Against <i>Staphylococcus aureus</i> ," <i>ASM</i> , May 2001. Poster No. A-4 , one page.	
	96.	Harding, I. et al. (2000). "Teicoplanin Therapy for <i>Staphylococcus Aureus</i> Septicaemia: Relationship Between Pre-Dose Serum Concentrations and Outcome," <i>JACS</i> 45:835-841.	
	97.	Heiselman, D. (1994). "Nosocomial Bloodstream Infections in the Critically Ill," <i>JAMA</i> 272(23):1819-1820.	
	98.	Hiramatsu, K. et al. (1997). "Dissemination in Japanese Hospitals of Strains of <i>Staphylococcus Aureus</i> Heterogeneously Resistant to Vancomycin," <i>Lancet</i> 350:1670-1673.	
	99.	Jabes, D. et al. (2001). "Efficacy of a Single Dalbavancin (DA) Dose Compared with Multiple Linezolid (LN) Doses against Penicillin-Resistant Pneumococci (PRSP) in a Lobar Pneumonia (LP) Model in the Immunocompetent Rat (IR)," <i>41st. ICAAC Abstracts</i> , Chicago, IL, September 22-25, 2001. Abstract No. B-989, p. 54.	
	100.	Jabes, D. et al. (December, 2000). " <i>In vitro</i> and <i>in vivo</i> Bactericidal Activity of the New Glycopeptide BI 397 and Correlations with Drug Concentrations," BioSearch Italia, S.P.A., San Antonio, December 2000, Poster No. F5 , one page.	
	101.	Jabes, D. et al. (2001). "Efficacy of a Single Dalbavancin (DA) Dose Compared with Multiple Vancomycin (VA) Doses against MRSA in the Rat Pouch Model of Infection," <i>41st. ICAAC Abstracts</i> , Chicago, IL. September 22 - 25, 2001. Abstract No. B-1654, pg. 68.	
	102.	Jabes, D. et al. (2001). "Efficacy of a Single Dalbavancin (DA) Dose Compared with Multiple Vancomycin (VA) Doses against MRSA in the Rat Pouch Model of Infection," <i>41st. ICAAC</i> , Chicago, IL. December, 2001. Poster No. B-1654 , one page.	
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	103.	Jabes, D. et al. (2003). "Efficacy of Dalbavancin Compared with Vancomycin and Linezolid in the Rat Granuloma Pouch Model of Staphylococcal Infection," <i>Symposium on Surgical Infections</i> , Como, Italy Poster No. P1 , one page.
	104.	Jain, R.K. (2003). "D-Ala-D-Lac Binding Is Not Required for the High Activity of Vancomycin Dimers Against Vancomycin Resistant Enterococci," <i>JACS</i> 125:8740-8741.
	105.	Jones, R. N. et al. (2001). "Activity and Spectrum Evaluation of Dalbavancin (V-Glycopeptide and BI397), A Novel "Glycopeptide" Class Antimicrobial," <i>41st ICAAC Abstracts</i> , Chicago, IL. September 22-25, 2001, Abstract No. 2276, pg. 200.
	106.	Jones, R. N. et al. (2001). "Activity and Spectrum Evaluation of Dalbavancin (V-Glycopeptide and BI397), A Novel "Glycopeptide" Class Antimicrobial," <i>41st ICAAC</i> Chicago, IL. December, 2001, Poster No. 2276 , one page.
	107.	Jones, R.N. et al. (2001). " <i>In Vitro</i> Evaluation of BI 397, a Novel Glycopeptide Antimicrobial Agent," <i>Journal of Chemotherapy</i> 13(3):244-254.
	108.	Jordan, M.K. et al. (2002). "A Novel Use of Optimal Sampling Theory (OST) During Drug Development," <i>American Society of Clinical Pharmacology & Therapeutics</i> , Atlanta, GA, March 2002. Poster , one page.
	109.	Kenny, M.T. et al. (1995). "In Vitro Activity of the Semisynthetic Glycopeptide Amide MDL 63,246," <i>Antimicrobial Agents and Chemotherapy</i> 39(7):1589-1590.
	110.	Lefort, A. et al. (2002). "Activity of Dalbavancin (BI-397) In Vitro and in Experimental Endocarditis due to Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA) Susceptible or Intermediate to Glycopeptides (GISA)," <i>42nd ICAAC Abstracts</i> , San Diego, CA, September 27 - 30, 2002. Abstract No. B-278, page 33.
	111.	Leighton, A. et al. (2001). "Dalbavancin: Phase I Single and Multiple-Dose Placebo Controlled Intravenous Safety, Pharmacokinetic Study in Healthy Volunteers," <i>41st ICAAC Abstracts</i> , Chicago, IL. September 22-25, 2001. Abstract No. 951, pg. 25.
	112.	Leighton, A. et al. (2001). "Dalbavancin: Phase I Single and Multiple-Dose Placebo Controlled Intravenous Safety, Pharmacokinetic Study in Healthy Volunteers," <i>41st ICAAC</i> , Chicago, IL. December, 2001. Poster No. 951 , one page.
	113.	Leighton, A. et al. (2001). "Stringent Audiology Assessments in a Healthy Volunteer Study with the Glycopeptide Dalbavancin," <i>41st ICAAC Abstracts</i> , Chicago, IL, September 22 - 25, 2001. Abstract No. A-2192, pg. 37.
	114.	Leighton, A. et al. (2001). "Stringent Audiology Assessments in a Healthy Volunteer Study with the Glycopeptide Dalbavancin," <i>41st ICAAC</i> , Chicago, IL, December, 2001. Poster No. A-2192 , one page.
	115.	Lopez, S. et al. (2003). " <i>In Vitro</i> Susceptibility and Population Analysis of Staphylococci After Serial Passage at Sub-MIC Levels of Dalbavancin and Other Glycopeptides," <i>Clinical Microbiology and Infection</i> , 9(Supp. 1), pg. 375 Abstract No. P1539.

EXAMINER:	DATE CONSIDERED:
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	Applicant: CAVALERI et al.	
	Filing Date: Submitted herewith	Group Art Unit: Not Yet Assigned
	Mailing Date: April 16, 2004	

116.	Lopez, S. et al. (2003). "In Vitro Susceptibility and Population Analysis of Staphylococci After Serial Passage at Sub-MIC Levels of Dalbavancin and Other Glycopeptides," <i>ECCMID</i> , May, 2003. Poster No. P1539 , one page.
117.	Lyght, C.E. et al. eds. (1966). <u>The Merck Manual of Diagnosis & Therapy</u> 11th Edition, Merck Sharp & Dohme Research Laboratories pp. 799-862.
118.	Malabarba, A. and Ciabatti, R. (2001). "Glycopeptide Derivatives," <i>Current Medicinal Chemistry</i> 8(14):1759-1773.
119.	Malabarba, A. and Donadio, S. (1999). "BI-397: Glycopeptide Antibiotic," <i>Drugs of the Future</i> 24(8):839-846.
120.	Malabarba, A. et al. (1987). "Synthesis and Biological Activity of Some Esters of the <i>N</i> -Acetylglucosaminyl Aglycone and of the Aglycone of Teicoplanin," <i>The Journal of Antibiotics</i> 40(11):1572-1587.
121.	Malabarba, A. et al. (1995). "New Semisynthetic Glycopeptides MDL 63,246 and MDL 63,042, and Other Amide Derivatives of Antibiotic A-40,926 Active Against Highly Glycopeptide-Resistant VanA Enterococci," <i>Journal of Antibiotics</i> 48(8):869-883.
122.	Malabarba, A. et al. (1997). "Structural Modifications of Glycopeptide Antibiotics," <i>Medicinal Research Reviews</i> 17(1):69-137.
123.	Malabarba, A. et al. (1998). "BI 397: A New Developmental Semisynthetic Glycopeptide Antibiotic," <i>Abstracts of the 38th ICAAC</i> September 24 - 27, 1998, San Diego, CA Abstract No. F107 pg. 259.
124.	Mammen, M. et al. (1998). "Polyvalent Interactions in Biological Systems: Implications for Design and Use of Multivalent Ligands and Inhibitors," <i>Angew. Chem. Int. Ed.</i> 37:2754-2794.
125.	McGovern, S.L. et al. (2002). "A Common Mechanism Underlying Promiscuous Inhibitors from Virtual and High-Throughput Screening," <i>J. Med. Chem.</i> 45:1712-1722.
126.	McOmie, J.F.W. ed. (1973). <u>Protective Groups in Organic Chemistry</u> Plenum Press: New York, NY p. xi (Table of Contents Only.)
127.	Neu, H.C. (1992). "The Crisis in Antibiotic Resistance," <i>Science</i> 257:1064-1073.
128.	Newell, K.A. et al. (1998). "Incidence and Outcome of Infection by Vancomycin-Resistant <i>Enterococcus</i> Following Orthotopic Liver Transplantation," <i>Transplantation</i> . 65(3):439-442.
129.	Nicolaou, K.C. et al. (1999). "Chemistry, Biology, and Medicine of the Glycopeptide Antibiotics," <i>Angew. Chem. Int. Ed.</i> 38:2096-2152.
130.	Nicolaou, K.C. et al. (2000). "Target-Accelerated Combinatorial Synthesis and Discovery of Highly Potent Antibiotics Effective Against Vancomycin-Resistant Bacteria," <i>Angew. Chem. Int. Ed.</i> 39(21):3823-3828.

EXAMINER:	DATE CONSIDERED:
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	Mailing Date: April 16, 2004	

131.	Nicolaou, K.C. et al. (2001). "Synthesis and Biological Evaluation of Vancomycin Dimers with Potent Activity Against Vancomycin-Resistant Bacteria: Target-Accelerated Combinatorial Synthesis," <i>Chem. Eur. J.</i> 7(17):3824-3843.
132.	Nisbet, L.J. et al. (1986). "Discovery, Comparative Antibacterial Activity and Structure Elucidation of AAJ-271, a Novel Group of Glycopeptides," <i>26th Annual ICAAC</i> , New Orleans, LA October, 1986, Abstract No. 226, pg. 137.
133.	Ochalski, T.J. and Zuk, J. (1998). "Photoreflectance Studies of InGaAs/GaAs/AlGaAs Single Quantum Well Laser Structures," <i>Acta Phys. Pol.</i> 94(3):463-467.
134.	Omura, S. et al. (1984). "Effect of Ammonium Ion, Inorganic Phosphate and Amino Acids on the Biosynthesis of Protylonolide, a Precursor of Tylosin Aglycone," <i>The Journal of Antibiotics</i> , 37(5):494-502.
135.	Omura, S. et al. (1984). "Bioconversion and Biosynthesis of 16-Membered Macrolide Antibiotics. XXIX: Effect of Ammonium Ion, Inorganic Phosphate and Amino Acids on the Biosynthesis of Protylonolide, a Precursor of Tylosin Aglycon," (1984). <i>Chemical Abstracts</i> Abstract No. 51459t. 101:318.
136.	Pavlov, A.Y. and Preobrazhenskaya, M.N. (1998). "Synthesis and Antibacterial Activity of Derivatives of the Glycopeptide Antibiotic A-40926 <i>N</i> -Alkylated at the Aminoglucuronyl Moiety," <i>Journal of Antibiotics</i> 51(5):525-527.
137.	Popieniek, P.H. and Pratt, R.F. (1987). "A Fluorescent Ligand for Binding Studies with Glycopeptide Antibiotics of the Vancomycin Class," <i>Analytical Biochemistry</i> 165:108-113.
138.	Printsevskaya, S.S. et al. (2002). "Synthesis and Mode of Action of Hydrophobic Derivatives of the Glycopeptide Antibiotic Eremomycin and Des-(<i>N</i> -methyl-D-leucyl)eremomycin Against Glycopeptide-Sensitive and -Resistant Bacteria," <i>J. Med. Chem.</i> 45:1340-1347.
139.	Printsevskaya, S.S. et al. (2003). "Role of the Glycopeptide Framework in the Antibacterial Activity of Hydrophobic Derivatives of Glycopeptide Antibiotics," <i>J. Med. Chem.</i> 46:1204-1209.
140.	Rao, J. and Whitesides, G.M. (1997). "Tight Binding of a Dimeric Derivative of Vancomycin with Dimeric L-Lys-D-Ala-D-Ala," <i>J. Am. Chem. Soc.</i> 119:10286-10290.
141.	Rao, J. et al. (1999). "Binding of a Dimeric Derivative of Vancomycin to L-Lys-D-Ala-D-Lactate in a Solution and at a Surface," <i>Chemistry & Biology</i> 6:353-359.
142.	Rao, J. et al. (1999). "Using Surface Plasmon Resonance to Study the Binding of Vancomycin and Its Dimer to Self-Assembled Monolayers Presenting D-Ala-D-Ala," <i>J. Am. Chem. Soc.</i> 121:2629-2630.
143.	Richards, M.J. et al. (1999). "Nosocomial Infections in Medical Intensive Care Units in the United States," <i>Crit. Care. Med.</i> 27(5): 887-892.
144.	Riva, E. et al. (1987). "Column Purification and HPLC Determination of Teicoplanin and A40926," <i>Chromatographia</i> 24:295-301.

EXAMINER:	DATE CONSIDERED:
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		Mailing Date: April 16, 2004	
	145.	Romano, G. et al. (2003). "In Vitro Antibacterial Properties of Dalbavancin and Reference Compounds Against Recent Clinical Isolates," <i>Symposium on Surgical Infections</i> Como, Italy Poster P3 , one page.	
	146.	Roy, R.S. et al. (2001). "Direct Interaction of a Vancomycin Derivative with Bacterial Enzymes Involved in Cell Wall Biosynthesis," <i>Chemistry & Biology</i> 8/11:1095-1106.	
	147.	Schäfer, M. et al. (1996). "The Molecular and Crystal Structure of the Glycopeptide A-40926 Aglycone," <i>Helvetica Chimica Acta</i> 79:1916-1924.	
	148.	Schwyzer, R. et al. (1955). "Über Aktivierte Ester," <i>Helv. Chim. Acta.</i> 38(7/8):69-79. (English abstract pg. 79.)	
	149.	Seltzer, E. et al. (2003). "Dalbavancin: Phase 2 Demonstration of Efficacy of a Novel, Weekly Dosing Regimen in Skin and Soft Tissue Infections," <i>ECCMID</i> , May 2003, Abstract No. O143, pg. 22.	
	150.	Selva, E. et al. (1988). "A40926 Aglycone and Pseudoaglycones: Preparation and Biological Activity," <i>The Journal of Antibiotics</i> 41(9):1243-1252.	
	151.	Shopsin, B. et al. (2000). "Prevalence of Methicillin-Resistant and Methicillin-Susceptible <i>Staphylococcus Aureus</i> in the Community," <i>The Journal of Infectious Diseases</i> 182:359-362.	
	152.	Sieradzki, K. et al. (1998). "Decreased Susceptibilities to Teicoplanin and Vancomycin Among Coagulase-Negative Methicillin-Resistant Clinical Isolates of Staphylococci," <i>Antimicrobial Agents and Chemotherapy</i> 42(1): 100-107.	
	153.	Sieradzki, K. et al. (1999). "The Development of Vancomycin Resistance in a Patient with Methicillin-Resistant <i>Staphylococcus Aureus</i> Infection," <i>NEJM</i> . 340(7): 517-523.	
	154.	Staroske, T. and Williams, D.H. (1998). "Synthesis of Covalent Head-to-Tail Dimers of Vancomycin," <i>Tetrahedron Letters</i> 39:4917-4920.	
	155.	Stephan, J. et al. (2003). "Worldwide Assessment of Dalbavancin Activity and Spectrum (2002)," <i>43rd Annual ICAAC</i> , Chicago, IL, September 14-17, 2003, Poster #F-2107 , one page.	
	156.	Stogniew, M. et al. (2003). "Pharmacokinetic Attributes of Dalbavancin: Well Distributed and Completely Eliminated with Dual Routes of Elimination," <i>ECCMID</i> , May 2003, Poster , one page.	
	157.	Stogniew, M. et al. (2003). "Attributes of Dalbavancin: Well Distributed, Weekly Dosing, and Completely Eliminated," <i>ECCMID Clinical Microbiology and Infection</i> , Abstract No. P1225, 9(Supp. 1) pg. 291.	
	158.	Sundram, U.N. and Griffin, J.H. (1996). "Novel Vancomycin Dimers with Activity Against Vancomycin-Resistant Enterococci," <i>J. Am. Chem. Soc.</i> 118:13107-13108.	
	159.	Süssmuth, R. D. (2002). "Vancomycin Resistance: Small Molecule Approaches Targeting the Bacterial Cell Wall Biosynthesis," <i>ChemBioChem</i> 3:295-298.	
	160.	Tenover, F.C. et al. (2001). "Increasing Resistance to Vancomycin and Other Glycopeptides in <i>Staphylococcus Aureus</i> ," <i>Emerging Infectious Diseases</i> 7(2): 327-332.	
EXAMINER:		DATE CONSIDERED:	
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Group Art Unit: Not Yet Assigned

Mailing Date: April 16, 2004

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| 161. | Verhoef, J. (1993). "Prevention of Infections in the Neutropenic Patient," <i>Clinical Infectious Diseases</i> 17(S2):S359-S367. |
| 162. | Walsh, C. (2000). "Molecular Mechanisms That Confer Antibacterial Drug Resistance," <i>Nature</i> 406:775-781. |
| 163. | Walsh, C.T. et al. (1996). "Bacterial Resistance to Vancomycin: Five Genes and One Missing Hydrogen Bond Tell the Story," <i>Chemistry & Biology</i> 3:21-28. |
| 164. | White, R.J. et al. (2000). "V-Glycopeptide: Phase 1 Single and Multiple-Dose Placebo Controlled Intravenous Safety, Pharmacokinetic, and Pharmacodynamic Study in Healthy Subjects," <i>40th ICAAC</i> , Toronto, CN. September 17 - 20, 2000, Poster No. 2196 , one page. |
| 165. | White, R.J. et al. (2000). "V-Glycopeptide: Phase 1 Single and Multiple-Dose Placebo Controlled Intravenous Safety, Pharmacokinetic, and Pharmacodynamic Study in Healthy Subjects," <i>40th ICAAC Abstracts</i> , Toronto, CN. September 17-20, 2000, Abstract No. 2196, one page. |
| 166. | Williams, D.H. et al. (1998). "An Analysis of the Origins of a Cooperative Binding Energy of Dimerization," <i>Science</i> 280:711-714. |
| 167. | Xu, R. et al. (1999). "Combinatorial Library Approach for the Identification of Synthetic Receptors Targeting Vancomycin-Resistant Bacteria," <i>J. Am. Chem. Soc.</i> 121:4898-4899. |
| 168. | Zerilli, L.F. et al. (1992). "Determination of the Acyl Moieties of the Antibiotic Complex A40926 and their Relation with the Membrane Lipids of the Producer Strain," <i>Rapid Communications in Mass Spectrometry</i> 6:109-114. |

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